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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,760	01/03/2002	Brett Finlay	UBCV-0006	9198

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WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER

SHANNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,760

Applicant(s)

FINLAY ET AL.

Examiner

Khatol S Shannan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36, 38, 49, 50, 52 and 90 is/are rejected.
- 7) ☒ Claim(s) 37, 39-48, 51 and 53-89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' amendment, received September 29, 2004 is acknowledged. Claims 33-35, 41-44, 46, 48-49, 55-58, 60 and 62 have been amended. New claims 63-90 have been added.
2. Currently claims 33-90 are pending and under consideration.
3. Applicants' Declaration in accordance with 37 C.F.R. 1.131, received 9/07/2004 is acknowledged. The Declaration by Dr. Brett Finlay filed on 9/07/2004 under 37 CFR 1.131 is sufficient to overcome the Li et al. reference.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Objections Withdrawn

5. Objection to the specification, made in paragraph 5 of the office action mailed March 5, 2004 is withdrawn in view of applicants' response.

Rejections Withdrawn

6. Rejections of claims 33-62 under 35 U.S.C. 112, first paragraph, made in paragraph 7 of the office action mailed March 5, 2004 is withdrawn in view of applicants' amendments.
7. Rejection of claims 33-62 under 35 U.S.C. 112, second paragraph, made in paragraph 9 of the office action mailed March 5, 2004 is withdrawn in view of applicants' amendments.

8. Rejection of claims 33- 36, 38, 45, 49, 50 and 59 under 35 U.S.C. 102(a) as being anticipated by Li et al. (Infection and Immunity Vol. 68, No.9, pp. 5090-5095, September 2000) is withdrawn in view of applicants' declaration.
9. Rejection of claims 33-62 under 35 U.S.C. 103(a) as being unpatentable over Li et al. in view of Little-van den Hurk et al. is withdrawn in view of applicants' declaration.

New Rejections

Claim Rejections - 35 USC § 103

10. Claims 33, 34, 35, 36, 38, 49, 50, 52 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allan et al. (US Patent 5,747,309) in view of Dean-Nystrom (Infection and Immunity, vol.66, no. 9, pp. 4560-4563, 1998).

The claims are drawn to a method of reducing colonization /shedding of enterohemorrhagic E. coli (EHEC) in a non-human mammal comprising administering a composition comprising an E.coli cell culture supernatant.

Allan et al. teach a method of preventing E. coli infection (i.e. reducing colonization/shedding of E.coli) in a non-human mammal comprising administering a composition comprising an E.coli cell culture supernatant (see abstract, claims, specially claims 20 and 48, columns 3, 6, 8, 9, 10). Allen et al. teach domestic animals such as bovine and ovine (see column 6, lines 38-46). Allen et al. teach culture supernatant (see column 10, lines 40-45), multiple strains of E. coli (see column 12). Allen et al. do not teach E.coli O157:H7. However, Dean-Nystrom et al. teach E.coli O157:H7 and intimin based vaccines for reduction of EHEC in cattle (see abstract)

It would have been *prima facie* obvious to a person of ordinary skill in the art at

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the time the invention was made to combine the methods of Allen et al. and Dean-Nystrom et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated to use the specific strains of E.coli taught by Dean-Nystrom et al, with the expectation of obtaining a composition containing EHEC to reduce colonization of EHEC in cattle.

Conclusion

11. No claims are allowed.

Claims 33, 34, 35, 36, 38, 49, 50, 52 and 90 are rejected.

Claims 37, 39-48, 51 and 53-89 are objected to as being depended from rejected claims 33 and 34.

12. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnan-Shah, BS, Pharm, MS
Biotechnology Patent Examiner

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July 7, 2005



MARK NAVARRO
PRIMARY EXAMINER